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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application

Lisa A. Paige et al.

Serial No.

09/429,331

Filed

October 28, 1999

For

METHOD OF PREDICTING THE ABILITY

OF COMPOUNDS TO MODULATE THE BIOLOGICAL

ACTIVITY OF RECEPTORS

Examiner

: Wessendorf, Teresa D.

Attorney Docket

102555-400

Group Art Unit Confirmation No.

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I hereby certify that this correspondence is being sent by facsimile transmission to the United States Patent and Trademark Office at telephone number (703) 872-9306 on 17 June 2004

Βv

Todd E. Garabedian, Ph.D. Registration No. 39,197

Attorney for Applicants

## REPLY TO RESTRICTION REQUIREMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In Reply to the Restriction/Election Requirement mailed April 7, 2004, Applicants submit the following remarks:

At the outset, the undersigned attorney submits that he is filing this Response to Restriction Requirement in his representative capacity under 37 CFR §\$1.31, 1.33(b)(2), and 1.34. Applicants will file a change of power of attorney and a change of correspondence address shortly.

Applicants respectfully thank Examiner Wessendorf for discussing the species election in a telephonic interview with Applicants' representative on June 16, 2004. The interview was helpful in clarifying "test substance" species election, as discussed in more detail below.

### Restriction Requirement

In the Restriction/Election Requirement, the Examiner grouped pending claims 1-134 into nineteen categories as follows:

Group I, Claims 1-29, 35-39, 43, 45-58, 70-72, 81, 83 and 99-101, drawn to a method of predicting the receptor-modulating activity of a compound;

Group II, Claims 30, 32-33 and 59-63, drawn to a peptide

Group III, Claims 31, 42 and 64-69, drawn to a panel;

Group IV, Claims 34, 40-41, 44, 80, 82, 86-89 and 96-98 drawn to a non-naturally occurring peptide;

Group V, Claims 73-77, drawn to a method of antagonizing the activation of a nuclear receptor in a cell;

Group VI, Claim 78, drawn to a method of screening for an agonist of a receptor requiring a co-activator;

Group VII, Claim 79, drawn to a method of screening for ligands specifically to ER beta;

Group VIII, Claim 84, drawn to a method of identifying an oligomeric molecule which modulates G-protein coupled receptor, specific to the activation state of G-alpha subunit;

Group IX, Claim 85, drawn to a method of identifying an oligomeric molecule which modulates G-protein coupled receptor, indifferent to the activation state of G-alpha subunit;

Group X, Claims 90-95, drawn to a method of identifying modulator of a GPCR comprising assaying potential modulators;

Group XI, Claims 102-117, drawn to a method of identifying a substance as an agonist or antagonist using reporter protein moiety;

Group XII, Claims 118-122, drawn to a method of identifying a substance as an agonist or antagonist of GPCR using doror fluorophore.

Group XIII, Claim 123, drawn to a method of identifying a substance as an agonist or antagonist of GPCR using G-alpha subunit in a fusion protein.

Group XIV Claim 124 drawn to a method of identifying a substance as an agonist or antagonist of GPCR wherein the fusion protein comprising a peptide binds in an activation state-specific manner.

Group XV, Claim 125, drawn to a method of identifying a substance as an agonist or antagonist of GPCR using library of cells.

Group XVI, Claims 126-130, drawn to a known method of identifying a substance as an agonist or antagonist of GPCR with modifying step of expressing a chimeric.

Group XVII, Claim 131, drawn to a known method of identifying a substance as an agonist or antagonist of GPCR with modifying step of expressing a chimeric using a library of cells.

Group XVIII, Claim 132, drawn to an assay.

Group XIX, Claims 133-134, drawn to a method of determining whether a substance is an agonist or antagonist of a receptor where the co-activator of said receptor is unknown.

Applicants herein elect without traverse the claims of Group I, e.g., claims 1-29, 35-39, 43, 45-48, 70-72, 81, 83, and 99-101, drawn to a method predicting the receptor-modulating

activity of a compound. Moreover, Applicants reserve the right to file divisional applications on the non-elected claims pursuant to 35 USC \$121 and claiming priority to this application under 35 USC \$120.

#### Species Election

The Examiner further required Applicants to elect one species from subgroup A through H if Group I is elected. In response to the Species Election, Applicants elect the following species:

- A. Estrogen receptor beta (ER-beta) as the Receptor;
- B. Tamoxifen as the Ligand;
- C. 4-OH Tamoxifen-liganded receptor as the Reference Conformation;
  - D. Oligopeptide library as the Combinatorial Library;
  - E. In vitro screening as the Screening step;
  - F. Estradiol as the Reference substance;
- G. The peptide family outlined in Table 10 as the Panel species.

With respect to selection of a species of "test substances" (Species E on page 6 of the Official Action), Applicants submit that a test substance may be any substance with unknown receptor modulating activity. As discussed with Examiner Wessendorf or June 16, 2004, the claims recited in Group I selected above are

directed to a method of predicting the receptor-modulating activity of a compound (the "test substance"). The test substance and its receptor modulating activity are not known before the claimed method is performed. Thus, a species of "test substance" cannot be chosen because it is the test substance that is evaluated for its receptor modulating activity. Accordingly, Applicants respectfully request that the species election requirement pertaining to "test substances" be withdrawn.

Applicants submit that claims 1-29, 35-39, 43, 45-58, 70-72, 81, 83, and 99-101 read on the above species elections.

Any fees due with this Reply may be charged to Deposit
Account 23-1665 under Customer Number 27267.

If a telephone conference would aid in the continued prosecution of this application, the Examiner is invited and encouraged to contact Applicants' representative at the telephone number listed below.

Respectfully submitted,

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